

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problems Mailbox.**

THIS PAGE BLANK (USPTO)



PCT/GB 00 / 03 1 15
10/09578
GB00/03115
INVESTOR IN PEOPLE

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

REC'D 12 SEP 2000

WIPO PCT

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

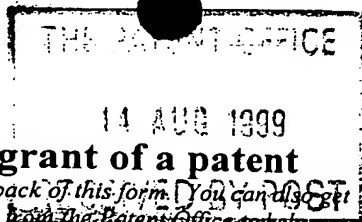
Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

Signed

AmBrewster

Dated 29 August 2000

**PRIORITY
DOCUMENT**
SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH RULE 17.1(a) OR (b)



The
Patent
Office

1/77

16AUG99 E469563-2 D02866
P01/7700 0.00 - 9919170.2

The Patent Office

Cardiff Road
Newport
Gwent NP9 1RH

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from The Patent Office to help you fill in this form)

1. Your reference	FEMI / P20403GB		
2. Patent application number (The Patent Office will fill in this part)	14 AUG 1999		9919170.2
3. Full name, address and postcode of the or of each applicant (underline all surnames)	Femcare (Cyprus) Limited Meliza Court, 4th & 7th Floors 229 Archbishop Makarios 111- Avenue Limassol Cyprus		
Patents ADP number (if you know it)			
If the applicant is a corporate body, give the country/state of its incorporation	Cyprus		
4. Title of the invention	APPLICATOR FOR SURGICAL CLIPS		
5. Name of your agent (if you have one)	ERIC POTTER CLARKSON		
"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)	PARK VIEW HOUSE 58 THE ROPEWALK NOTTINGHAM NG1 5DD		
Patents ADP number (if you know it)	1305010		
6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number	Country	Priority application number (if you know it)	Date of filing (day / month / year)
7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application	Number of earlier application		Date of filing (day / month / year)
8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:	YES		
a) any applicant named in part 3 is not an inventor; or b) there is an inventor who is not named as an applicant, or c) any named applicant is a corporate body. See note (d)			

6486096001 ✓

✓

APPLICATOR FOR SURGICAL CLIPS

The present application relates to applicators for surgical clips and more particularly to applicators for ligation clips.

5

Certain known applicators for clips use a push rod and associated link mechanism to cause rotation of an articulated jaw to produce compression forces on a clip and to thereby compress the clip causing it to close preferably with a latching action. The compression forces on the relatively slender central rod produce the risk of buckling with consequent lost motion. In addition, the mechanical force from the link causes radial reaction forces and consequent friction at the interface between the push rod and the outer tube.

15 For known applicators, this creates a requirement that the applicator must be made from high grade components which will withstand such forces and be able to perform many clip closure operations.

20 Additionally such designs with rotational closure forces usually require a clip to be inserted into the jaws of the applicator prior to clip closure. Thus, the applicator can only apply one clip at a time.

It is an object of the present invention to provide an applicator for surgical clips which is of a simpler, more robust design to such known applicators.

25

It is a further object of the preferred embodiment of the present invention to provide an applicator which can store and be used to apply a multiplicity of clips.

30 Such an applicator may be partially or completely disposable.

Said elongate inner member preferably includes stop means operable to provide opposing mechanical forces to oppose the force on a surgical clip by said outer member to create closure of the clip.

5 The present invention also provides a magazine storage system for an applicator for surgical clips, said magazine storage system comprising a plurality of surgical clips stored in a single column array within an elongate tube, said elongate tube comprising means at a proximal end thereof for attachment to a handle, said elongate tube means comprising
10 an inner member and an outer member, said inner and outer members being slideable relative to each other, said inner and outer members being shaped to retain said plurality of surgical clips and said inner and outer members having at a distal end thereof co-operating surfaces shaped to cause said surgical clip to be forced from an open to a closed position
15 when said inner and outer members are moved relative to each other.

Preferably the magazine includes spring means positioned within said inner member, said spring means being operative to urge said plurality of surgical clips from said proximal to said distal end of said elongate tube.

20 The outer member preferably comprises at the distal end a ledge shaped stop means to arrest movement of said plurality of surgical clips, said ledge shaped stop means providing leverage to effect closure of said clip when said outer member is moved relative to said inner member.

25 Preferably a ratchet stop means is provided in said inner tube, said ratchet stop means being positioned between said spring means and said plurality of surgical clips. Said ratchet stop means being moveable by said spring means in a direction from said proximal to said distal end of said elongate
30 tube, said ratchet stop means being co-operative with a corresponding

Figure 10 shows the barrel of Figure 9 in end view;

5 Figure 11 shows the barrel portion of the applicator in an exploded view;

Figure 12 shows the handle portion of the applicator in partial cross-section showing the spring actuated first and second levers; and

10 Figure 13 shows schematically a perspective view of the barrel assembly.

With reference now to the drawings, Figure 1 shows a surgical clip
15 applicator according to the present invention.

The applicator 10 comprise a handle portion 12 and a barrel portion 14. Within the handle portion 12 two levers 16 and 18 are located. The lever 16 in operation indexes the clips down the barrel portion 14 as explained
20 hereinafter and the lever 18 provides the operating force to effect closure of the clip.

The mechanical detail of the handle portion 12 and the barrel portion 14 are shown in Figure 2.

25 The lever 16 is shown in two positions 16 and 16'. In position 16', the clips 140 in barrel section 14 are fed forwardly as will be explained hereinafter.

With reference to Figures 4 and 5, the barrel section is shown in isolation from the handle 12. The handle lever 18 operates on shoulder 1410 to move inner tube 143.

5 Handle portion 12 is shown in greater detail in Figures 6 to 8.

The handle portion 12 may be disposable or may be reusable but preferably the barrel section 14 is disposable and is supplied in a "sterilised form for each operation".

10

The barrel portion 14 is preferably circular in cross-section. The barrel 14 may be rotated to always be in a suitable orientation by the surgeon so that the handle 12 may always be held in a suitable position allowing easy operation of lever 18.

15

With reference now to Figure 11, a preferred example of the barrel portion 14 is shown in exploded form.

20 The clips 140 are not shown for ease of illustration but will normally be present as shown in previous figures.

The barrel portion 14 comprises an outer tubular portion 141 which comprises a generally circular cross-section tube with the end operational portion 1402 formed integrally at the distal end.

25

Within the tube 141 is the inner tube 143 which also forms a magazine to house the clips 140. The inner tube 143 is formed integrally with the operational closure means 1406.

The other is the optional clip retention feature 1405, 1407 which provides a side grip on the clip to grip the clip by its lower jaw silicone rubber lining.

5 The superior features of the new applicator design are now summarised.

1. The axial sliding of two components (141; 143) of the shaft is used as a reliable and simple way to transmit actuation force from the operator interface to the clip closing jaws.

10

2. The outer tube (duck tube) (141) extended to form the clip tray 1403 and jaw forms the tension link. The inner channel 143 is the compression link exploiting the superior compression stability of this member.

15

3. Within the central core (channel) multiple clips 140 are stored for consecutive advancing and closing.

20

The system depends on the relationship between the profile of the upper jaw of the clip, the angle of the end portion 1402 of the outer tube 141 and the profile at the end of the channel (1406) during sliding movement of the two latter items.

25

An optional clip retention device (1405, 1407) is included in the clip jaw which grips on the silicone liner at the base of the clip so loss of control is avoided during surgery, but ensures easy release after closure.

30

Clip indexing along the channel utilises a one way frictional moving buffer and constant force spring (like staple gun).

2. Disposable barrel with clip closure functioning at surgical end but moving in a linear plane rather than through an arc.
3. The barrel and magazine indexed radially so the surgeon can adjust the angle of the jaws in relation to the hand position without changing angle of arm or conversely, if the surgeon has to change his arm position to avoid the patient, then he can still adjust the barrel to the correct working position.
4. A reusable handle with primary trigger for closing the clip, secondary trigger for both moving the clips in the barrel.
5. The handle/barrel arrangement and clip closure mechanism allows the surgeon's hand to remain in constant relationship with the operation of the clip for accurate surgical procedures.
6. The applicator is pre-set at manufacture which avoids calibration and maintenance. Magazines with 2, 4, 6, 12 clips could be preloaded and sold as sterile packs for insertion into common handles in the theatre.
7. The principle could be used for the Filshie clip (British Patent No 2177748) with magazines suitably matched to clip size and common handle. In a preferred embodiment, different colour/identity marking on the magazines would be used to distinguish ligation clips from Filshie clips.
8. The elimination of calibration will reduce the cost of maintenance.

successive clips into the jaw for use; twin buttons 122 (only one shown in Fig 1) that release the barrel from the hand grip. In addition, a textured grip 1469 (Fig 13) on the rear end of the barrel allows this to be rotated to any convenient orientation relative to the pistol handle.

5

The handle may be held in either hand, stabilised by the thumb. The secondary trigger 16 is operated by the index finger and the remaining fingers are used to squeeze the trigger 18. The retainer release buttons 122 are operated by squeezing between the thumb and index finger. All controls require force to be applied in one direction only and return to their normal positions under the action of internal springs.

10

The principal actions required when using of the applicator system are listed below and described in the following paragraphs.

15

- Loading pistol with sterile barrel
- Loading first clip to jaw
- Closing/opening clip
- Latching clip
- 20 ▪ Releasing latched clip and loading next clip
- Ejecting used barrel from pistol

Loading pistol with sterile barrel

25 Barrels (14) are supplied completely enclosed in an individual sterile pack (not shown). If the cylindrical portion of the barrel is gripped in either hand, the part of the pack covering the end to be inserted into the handle may be torn and removed. If the handle is taken up, in either hand, the exposed part of the barrel may be fed into the nose of the handle. When
30 inserted approximately 20mm, a resistance will be felt. Increased

If it is desired to positively prevent inadvertent overtravel and consequent latching of the clip, the following procedure is required. With the pistol in either hand and the trigger 18 in relaxed position, the trigger 16 is lightly drawn back. An initial rotational movement will be perceived after which increased resistance will be felt. While maintaining the secondary trigger in this position, the trigger 18 is drawn back. The clip will close as before but further travel beyond the closed position will be prevented as long as the secondary trigger is engaged. When it is desired to allow further travel of the trigger 18 to latch the clip, the trigger 16 is released.

Latching clip

The clip may be latched by squeezing the trigger (18) to the full extent of travel. As explained above, this may be done directly from the initial position, (clip open), or from the intermediate position, (clip depressed). In all cases, it is important that the trigger 18 be squeezed to the fullest extent of travel once it is desired to latch the clip. After completion of latching, the trigger 18 is released and will return to the relaxed position. The clip will be retained in the jaw.

With reference to Figure 13, the shaped portion of the inner tube 1406 is preferably moved towards the end stop 1402 to effect closure of the clip as shown in Figure 9. This provides the relatively smooth closure action of the clip resulting in uniform distribution of pressure across the tissue being occluded by the clip.

When the clip has been positioned at the end of the barrel in a position to be actuated the portion 1406 of the inner tube contacts the upper jaw of the clip near to the hinge of the clip which will be opened by the pressure of the silicone lining of the clip. Thus, the portion 1406 acts as a stop to

CLAIMS

1. An applicator for surgical clips, said applicator comprising elongate
5 tube means, said elongate tube means including means for
attachment to an operating handle, said elongate tube means
comprising an inner member and an outer member, said inner and
outer members being slidable relative to each other, said inner
10 member and said outer member being shaped to retain at least one
surgical clip, said handle being operative to slide said inner
member relative to said outer member, said inner and outer
members having co-operating surfaces to cause said surgical clip to
be forced from an open to a closed position on operation of said
15 handle to slide said inner and outer members relative to each other.
2. An applicator for surgical clips as claimed in Claim 1 in which said
outer member comprises an elongate tube shaped at an end distal
from said handle to retain said surgical clip.
- 20 3. An applicator for surgical clips as claimed in Claim 2 in which said
shape of said distal end of said outer member comprises an angled
sloping platform on which said surgical clip rests, said sloping
platform also comprising a raised flange forming stop means for
said surgical clips.
- 25 4. An applicator for surgical clips as claimed in Claims 1 to 3 in
which said inner member comprises an elongate inner member,
said elongate inner member comprising means for storing said
multiplicity of surgical clips.

clips, said ledge shaped stop means providing leverage to effect closure of said clip when said outer member is moved relative to said inner member.

- 5 10. A magazine storage system for an applicator for surgical clips as claimed in claim 9 in which a ratchet stop means is provided in said inner tube, said ratchet stop means being positioned between said spring means and said plurality of surgical clips. Said ratchet stop means being moveable by said spring means in a direction from
10 said proximal to said distal end of said elongate tube, said ratchet stop means being co-operative with a corresponding ratchet means on said inner member to be prevented from movement in the opposite direction.
- 15 11. An applicator for surgical clips substantially as described with reference to the accompanying drawings.
- 20 12. A magazine storage system for surgical clips substantially as described with reference to Figures 3, 4, 5, 9, 10 and 11 of the accompanying drawings.

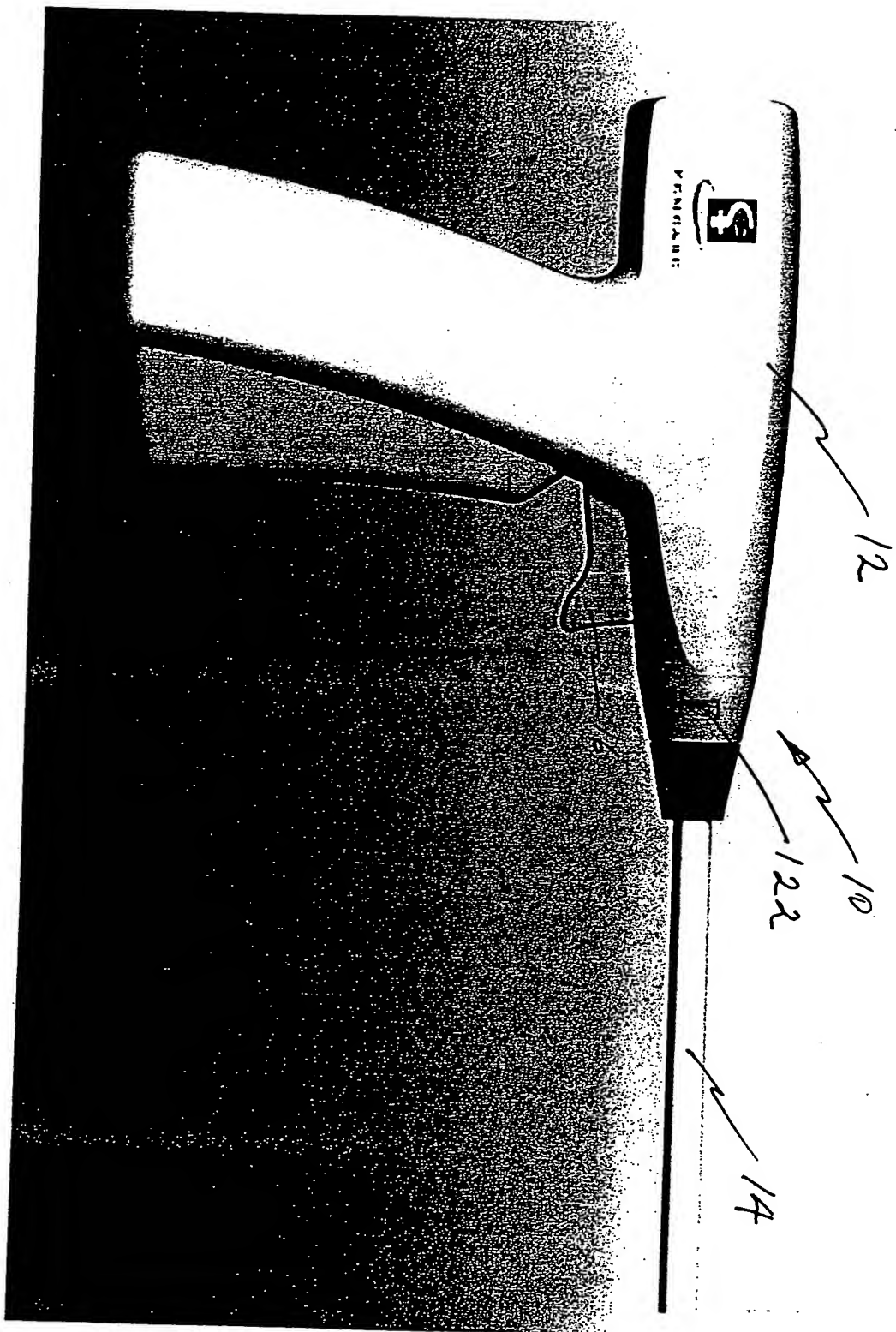


FIG. 1

Provisional

Fig 1

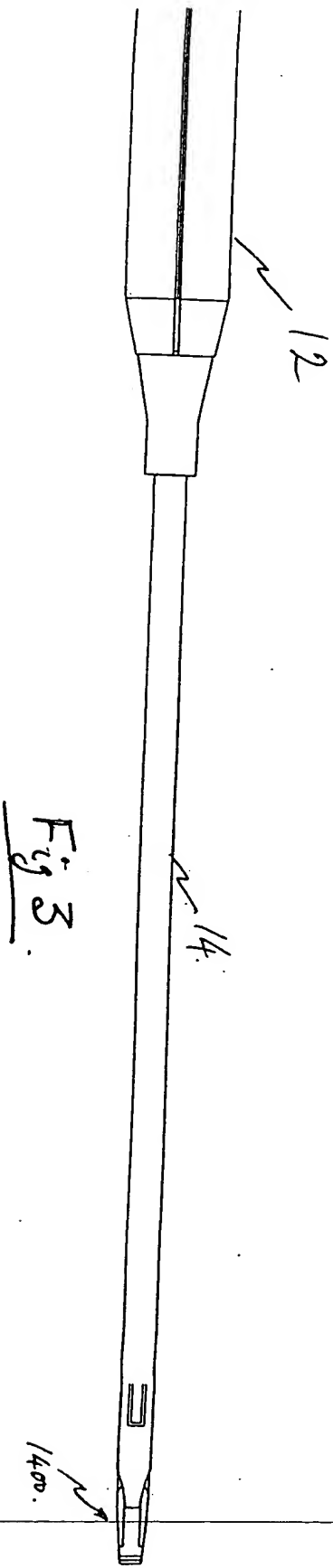
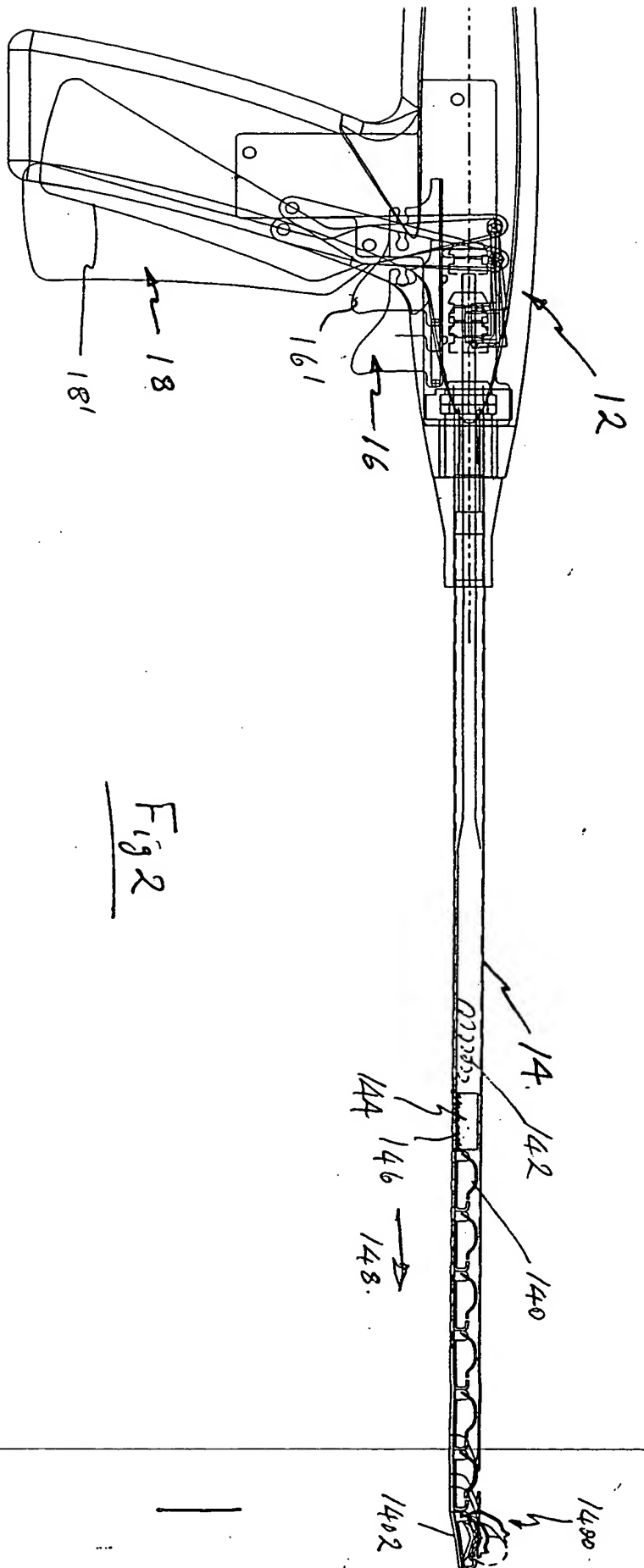


Fig 8

SECTION A-A

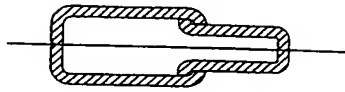


Fig 6

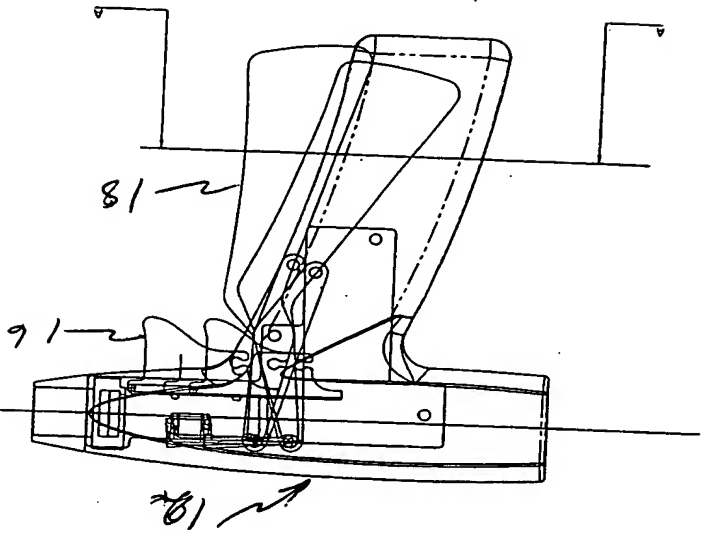


Fig 7

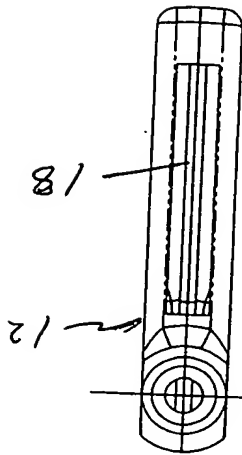


Fig 5

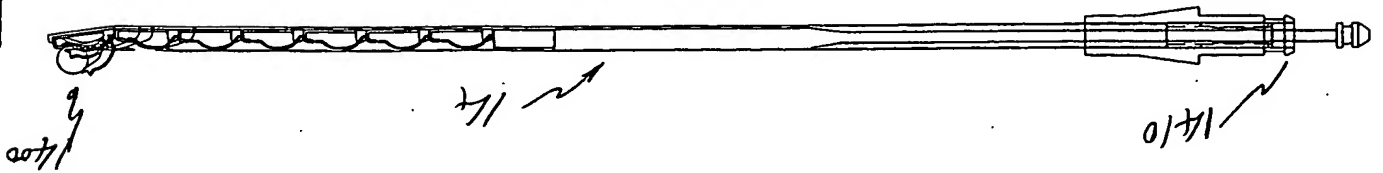
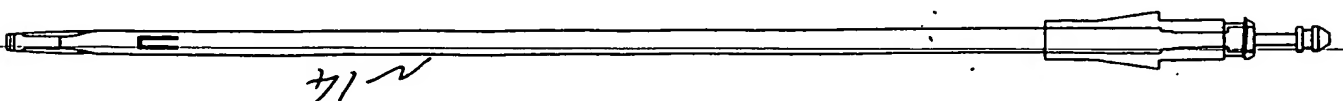


Fig 4



LIGATION CLIP

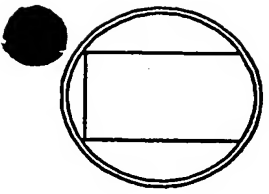
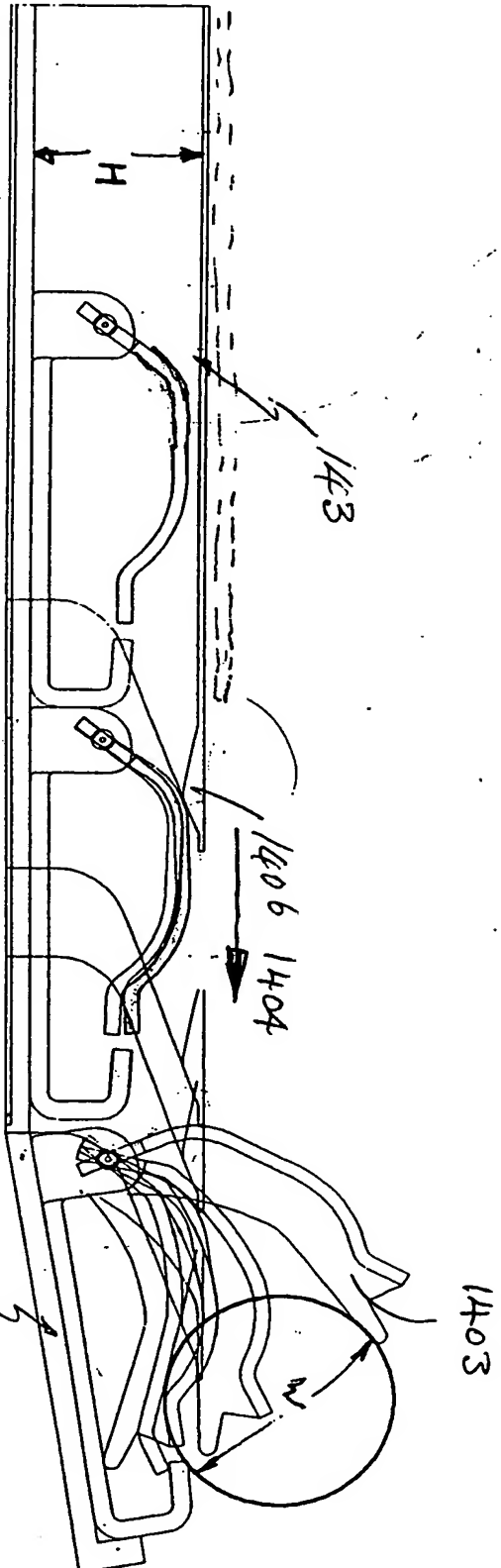


Fig 10



MARK 2 INTERIM CLIP

MARK 3 CLIP

Fig 9



© KASROUSE/FEMCARE

DEC 98

Provisional

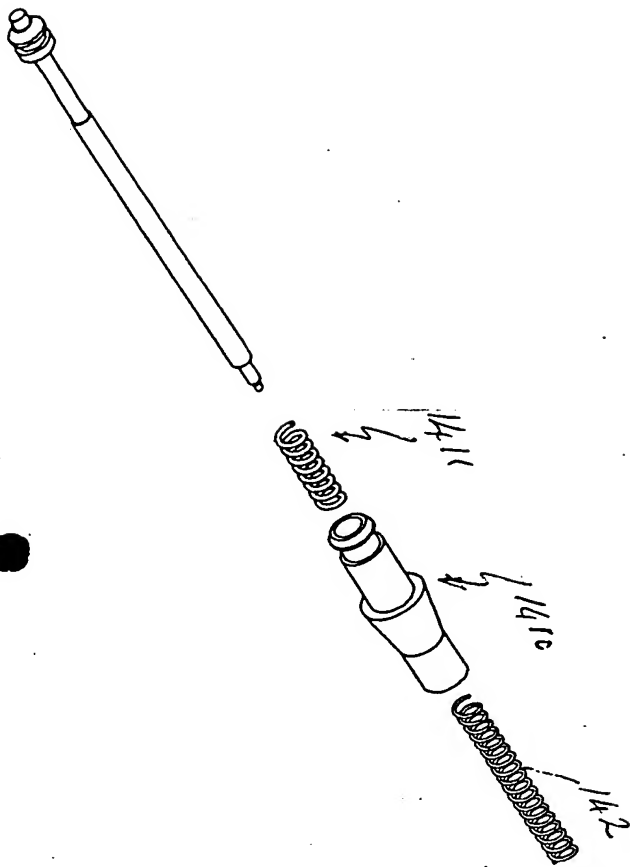
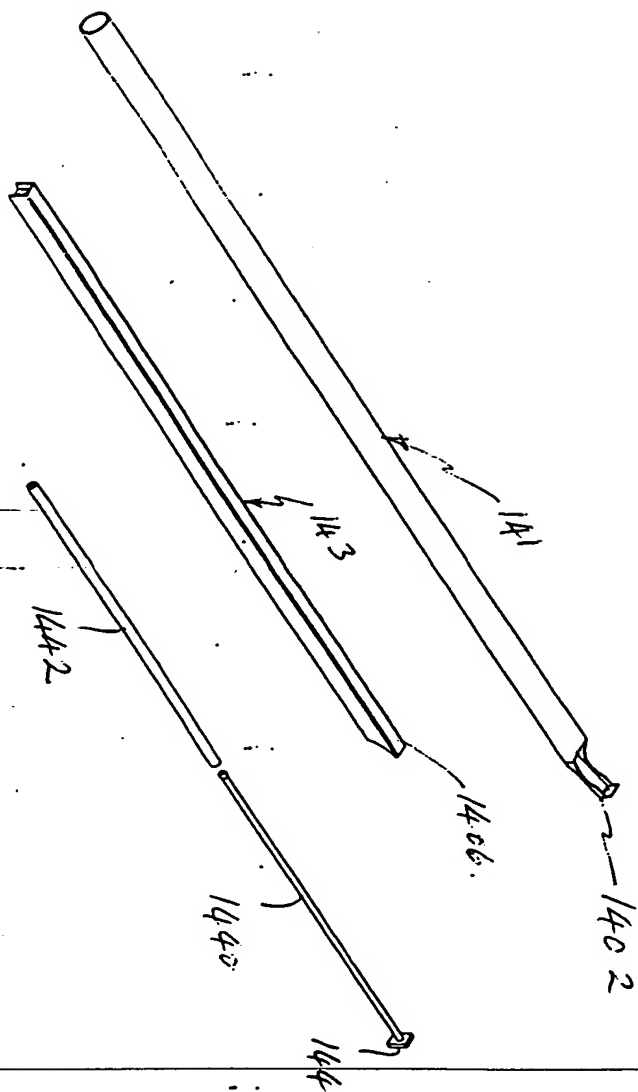


Fig 11



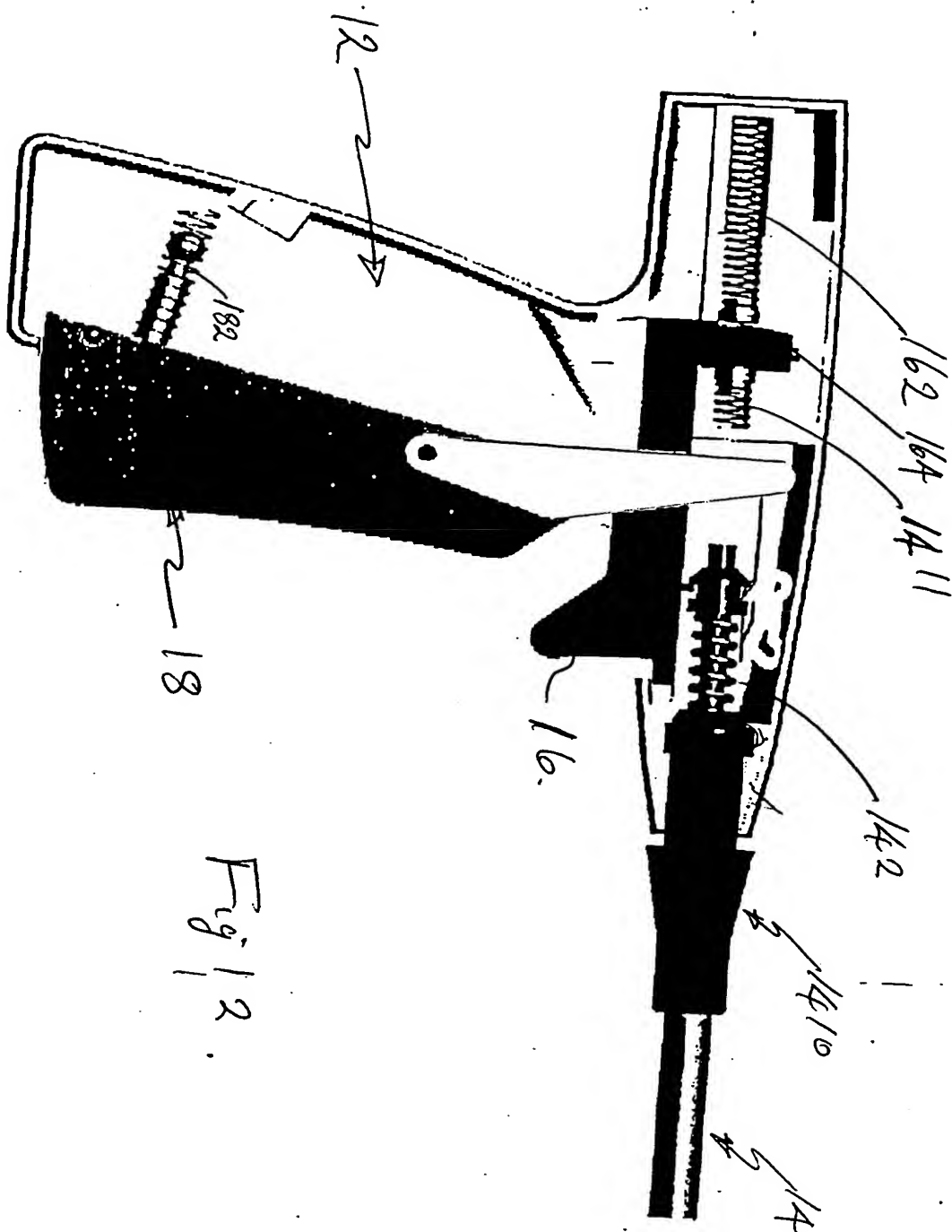


Fig 12.

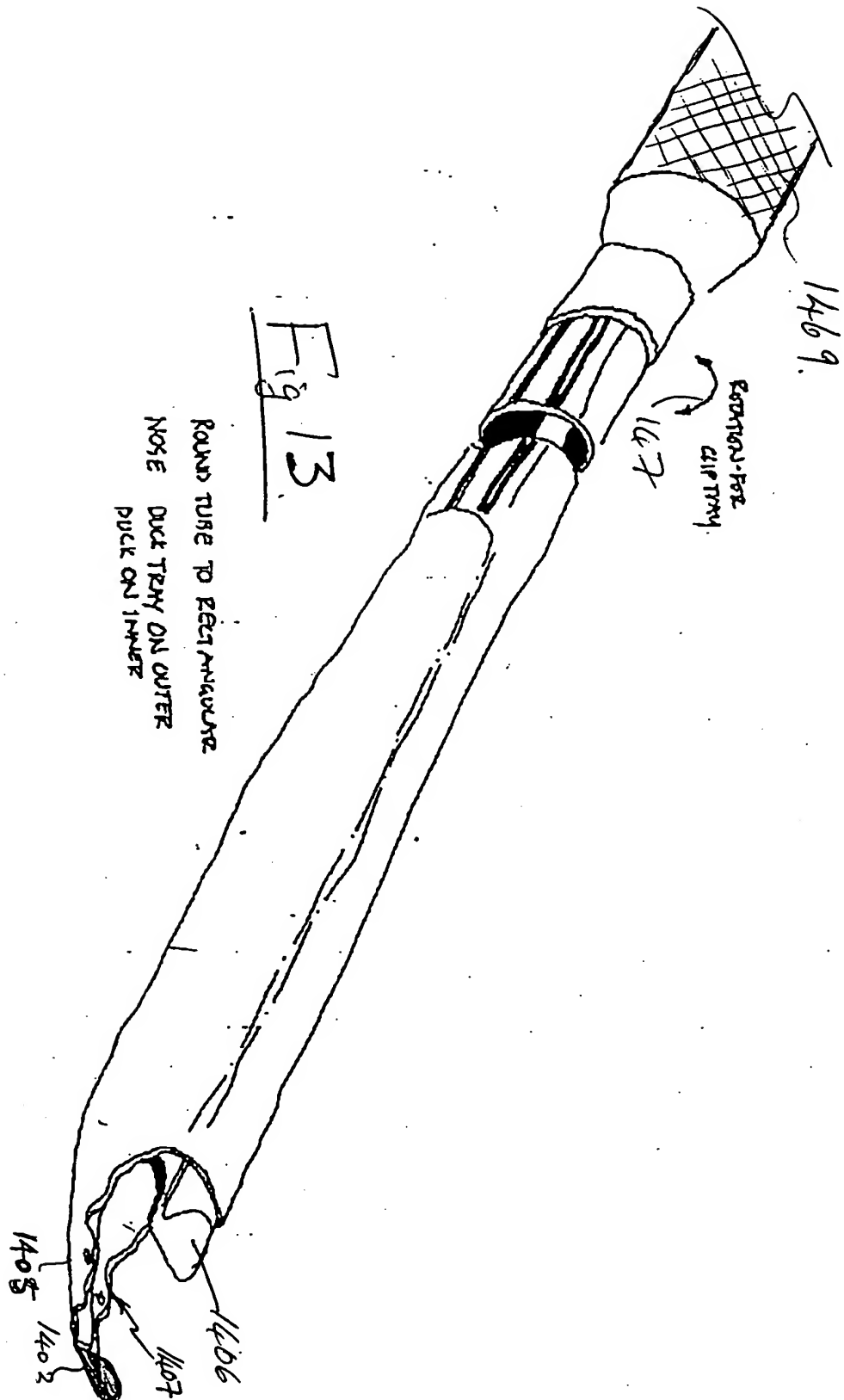


Fig 13.

ROUND TUBE TO RECTANGULAR
 NOSE DUCT TUBE ON OUTER
 PUCK ON INNER

THIS PAGE BLANK (USPTO)